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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,111	09/17/2003	Patrick Bernardelli	PC25382A	9341

28523 7590 01/12/2006

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,111	BERNARDELLI ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Applicant's amendment of 8-19-05 has been fully considered.

- The amended claim 1 and applicant's explanation have not overcome the previous rejection of 112/2nd, item (a).
- The deletion of "*derivatives thereof*" from claim 1 has overcome the previous rejection of 112/2nd, item (b).
- The amended claim 11 has overcome the previous rejection of 112/2nd, item (c).
- Applicant's argument has not overcome the previous rejection of 112/1st (Scope of Enablement).
- Applicant's argument has not overcome the previous rejection of Obviousness-type Double Patenting (ODP).
- Thus, only the rejection of 112/2nd, items (b) and (c) is withdrawn herein while the following rejections are maintained:
    - 112/2nd rejection, items (a) and (d) for claims 1-10 and 13-17.
    - 112/1st rejection (Scope of Enablement) for claims 13-16.
    - ODP rejection for claims 1-11 and 13-17.

Claim 12 is cancelled.

Claims 1-11 and 13-17 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-10 and 13-17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant explained that the alkyl group in R^2 got substituted with groups such as: OR^4, $COOR^4$, NR^4R^5,... etc., and variable R^4 was defined as another alkyl group substituted with $C(=O)R^7$, SO_2R^6, etc. Thus, applicant concluded that the definitions of R^2 and R^4 do not overlap with those of the second square bullet. However, the second square bullet also recites "optional substituents" which includes groups such as: OR^{4a}, $COOR^{4a}$, $NR^{4a}R^{5a}$,...etc. Variable $R^{4'}$ is **also an alkyl** group substituted with groups that are recited for R^4 (e.g. SO_2R^6). Thus, the alkyl group in the definitions of R^2 and/or R^4 can be substituted with two sets of substituents of different scope (or range). Therefore, it is unclear which set of substituents is intended for the alkyl or R^2.

Claims 2-10 and 13-17 are rejected as being dependent on claim 1.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 13-16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of AIDS (or HIV infection), does not reasonably provide enablement for the treatment of *T-cell related disease, osteioporosis, chronic obstructive pulmonary disease (or COPD), asthma, cancer, leukemia.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection is maintained for the reasons stated in the previous office action and for the following one.

Applicants cite several references linking PDE7 to asthma, COPD, T-cells, B-cells and osteoporosis. However, the cited references do not reveal a compound of spiro-quinazoline to the treatment of said disease. Furthermore, many of those references only provide speculation for those treatment.

It is still maintained that the specification does not provide sufficient guidance in term of *in-vivo* data for the treatment of many diseases recited in claims 13-16.

It is also maintained that the state of the art as evident by the teaching of Bricher et. al. (EP'994) only relates spiro-quinazoline compounds to the treatment of AIDS or HIV infection.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-11 and 13-17 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-26 of copending Application No. 2004/0214843 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons stated in the previous action and for the following ones:

- Applicants pointed out the difference between formula I of Pregrant US'843 and the instant formula I. However, such a difference is only a difference in scope. It is maintained that the instant formula I is still a **subgenus** of formula I of Pregrant US'843.
- Note, R^2 of the instant formula I can also represents Q^1-Q^2-Q^3-Q^4 which would correspond to R^1 as X^5Q^5 in Pregrant US'843.

- Applicants asserted that the disclosed species fall outside the scope of the instant formula I because their X_1 is –C-OCH_2CN. However, the two species in claims 22 and 23 of Pregrant US'843 do not have such a group.
- In claim 22, page 66 (Pregrant US'843) left column, the species on **line 49** is *5'-carboxymethoxy-8'-chloro-spiro[cyclohexane-1-4'(3',4'-dihydro)quinazolin]-2'(1'H)-one*, and the species on **line 52** is *5'-carboxypropoxy-8'-chloro-spiro[cyclohexane-1-4'(3',4'-dihydro)quinazolin]-2'(1'H)-one*. There is **no –CN** group in these species, and they **fall well within the scope** of the instant formula I.
- In claim 23, page 67 (Pregrant US'843) right column, the same two species are recited on lines 10 and 13.
- It appears that applicants must have considered different species, and thus, the argument had not been on point.
- Formula I of Pregrant US'843 also encompasses species recited in the instant claim 11, and thus, renders obvious claim 11 as well.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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01-07-06

Tamthom N. Truong
Examiner
Art Unit 1624

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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